



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 40399/177/NIHD

In re patent application of

Jerry M. Keith

Serial No. 07/542,149

Group Art Unit: 1814

Filed: June 22, 1990

Examiner: G. Bugaisky

For: PERTUSSIS TOXIN GENE:
CLONING AND EXPRESSION

RESPONSE UNDER 37 CFR §1.111

The Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

ATTN: BOX AF

Sir:

The following remarks are submitted in response to
the Examiner's June 11, 1993 Final Office Action.

Referring to page two of the Action, the Examiner has deemed insufficient the Declaration filed March 31, 1993 in support of the change of inventorship. The Examiner first asserts that the handwriting on some of the previously-submitted notebook pages does not appear to be the same throughout. It is believed that the Examiner is referring to the annotation at the top of each page indicating the exhibit page number. The Examiner is correct that those annotations are not original. Rather, those annotations appear to have been inserted when the original Keith Declaration was filed in this application in December 1991. The Declaration of Dr. Cieplak attached as Appendix 1 confirms that, other than those exhibit page number annotations, the handwriting on those notebook pages is Dr. Cieplak's handwriting. (A facsimile copy of Dr. Cieplak's declaration is appended, and will be supplemented with the original executed copy when received.)

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At page two of the Action, the Examiner also requests a copy of the front page of Dr. Cieplak's notebook and a copy of the table of contents. Such documents, however, are unavailable. Paragraph 2 of Dr. Cieplak's declaration states that, at the time that those experiments were carried out, it was his practice to record his notes in a looseleaf notebook. Hence, there is no notebook cover bearing Dr. Cieplak's name or table of contents page reflecting those experiments.

Also at page two of the Action, the Examiner requests corroboration of Dr. Cieplak's Declaration by Dr. Keith. Attached as Appendix 2 to this response is Dr. Keith's Declaration corroborating Dr. Cieplak's Declaration. (An unsigned copy of Dr. Keith's declaration is appended, and will be supplemented with the original executed copy when received.)

Lastly, the Examiner requested a further explanation of why Dr. Cieplak is being substituted as the sole inventor. The explanation is straightforward. As stated by Dr. Cieplak in Paragraph 3 of his Declaration:

[d]uring the course of my research at Rocky Mountain Laboratories, NIAID (Hamilton, Montana), I conceived that a mutation at the arginine 9 position of the amino acid sequence of the S1 subunit of *Bordetella pertussis* toxin could yield a substantially detoxified mutant comprising an epitope that contributes to immunoprotection against *Bordetella pertussis* toxicity. I subsequently discovered that such a mutation at the arginine 9 position in fact yielded a substantially detoxified mutant comprising an epitope that contributes to immunoprotection against *Bordetella pertussis* toxicity.

Under the rationale enunciated by the Federal Circuit in *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 18 USPQ2d 1016 (1991), it clearly appears that the claimed invention was conceived alone by Dr. Cieplak because he alone was the one who suggested the particular mutation at the arginine 9 position which resulted in the now-claimed invention. In a particularly germane passage of its decision, the *Amgen* panel stated that:

...[c]onception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property.

Id. at 1021.

Following the above reasoning, it is believed that conception did not occur until Dr. Cieplak suggested the actual structure of the mutant which is now claimed. The Keith Declaration corroborates the statement by Dr. Cieplak.

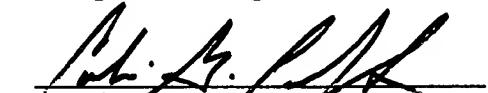
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In view of the foregoing, it is respectfully submitted that the requested inventorship amendment is proper and should be approved. Accordingly, the Examiner is requested to allow the claims and pass them to interference.

Respectfully submitted,

12/12/93

Date


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